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APPENDIX X.X.X.

GENERAL GUIDELINES FOR AQUATIC ANIMAL HEALTH SURVEILLANCE

Article 3.8.1.1.

Introduction and objectives

1. Surveillance is aimed at:

   - demonstrating the absence of *disease* or *infection*,

   - identifying events requiring notification as listed in Article 1.2.1.3. of the *Aquatic Code*,

   - determining the occurrence or distribution of endemic *disease* or *infection,* including changes to their incidence or prevalence (or its contributing factors), in order to:

     - provide information for domestic *disease* control programmes,

     - provide relevant *disease* occurrence information to be used by trading partners for qualitative and quantitative risk assessment.

   The type of surveillance applied depends on the desired outputs needed to support decision-making. Surveillance data determine the quality of *disease* status reports and should satisfy information requirements for accurate risk analysis both for *international trade* as well as for national decision-making.

2. Essential prerequisites to enable a Member Country to provide information for the evaluation of its animal health status are:

   a) that the particular Member Country complies with the provisions of Chapter 1.4.3. of the *Aquatic Code* on the quality and evaluation of the *Competent Authorities*;

   b) that, where possible, surveillance data be complemented by other sources of information (e.g. scientific publications, research data, documented field observations and other non-survey data);

   c) that transparency in the planning and execution of surveillance activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.2.1. of the *Aquatic Code*.

The following guidelines may be applied to all *diseases*, their agents and susceptible species as

listed in the *Aquatic Manual*, and are designed to assist with the development of surveillance methodologies. Where possible, the development of surveillance systems using these guidelines should be based on the relevant information in the individual *disease* chapters.

Article 3.8.1.2.

Definitions

The following definitions apply for the purposes of this Appendix:

Bias: A tendency of an estimate to differ from the true value of a population parameter.

Case definition: A case definition is a set of criteria used to distinguish a case animal or *epidemiological unit* from a non-case.

Early detection system: an efficient system for ensuring the rapid recognition of signs that are suspicious of a *listed disease*, or an *emerging disease* situation, or unexplained mortality, in *aquatic animals* in an *aquaculture establishment* or in the wild, and the rapid communication of the event to the *Competent Authority*, with the aim of activating diagnostic investigation with minimal delay. Such a system will include the following characteristics:

a) broad awareness, e.g. among the personnel employed at *aquaculture establishments* or involved in *processing*, of the characteristic signs of the *listed diseases* and *emerging diseases*;

b) veterinarians or *aquatic animal* health specialists trained in recognising and reporting suspicious *disease* occurrence;

c) ability of the *Competent Authority* to undertake rapid and effective *disease* investigation;

d) access by the *Competent Authority* to laboratories with the facilities for diagnosing and differentiating *listed* and *emerging diseases*.

Outbreak: An outbreak is a substantial increase in the occurrence of *disease* above the expected level at a given time in a given population.

Probability sampling: A sampling strategy in which every unit has a known non-zero probability of inclusion in the sample.

Sample: The group of elements (sampling units) drawn from a population, on which tests are performed or parameters measured to provide surveillance information.

Sampling unit: The unit that is sampled. This may be an individual animal or a group of animals (e.g. a pond). A list of all the sampling units comprises the sampling frame.

Sensitivity: The proportion of truly positive units that are correctly identified as positive by a

test.

Specificity: The proportion of truly negative units that are correctly identified as negative by a test.

Study population: The population from which surveillance data are derived. This may be the same as the target population or a subset of it.

Surveillance: The systematic ongoing collection, collation, and analysis of data, and the timely dissemination of information to those who need to know so that action can be taken.

Survey: An investigation about a defined population in which information is systematically collected within a defined time period.

Target population: The population about which conclusions from analysing data are to be inferred.

Test: A procedure used to classify a unit as either positive, negative or suspect with respect to an *infection* or *disease*.

Article 3.8.1.3.

Principles of surveillance

1. Types of surveillance

    a) Surveillance may be based on many different data sources and can be classified in a number of ways, including:

        i) the means by which data are collected (targeted versus non-targeted);

        ii) the *disease* focus (pathogen-specific versus general surveillance); and

        iii) the way in which units for observation are selected (structured surveys versus non-random data sources).

    b) Surveillance activities include:

        i) structured population-based surveys, such as:

            - systematic sampling at slaughter;

            - random surveys;

        ii) structured non-random surveillance activities, such as:

            - *disease* reporting or notifications;

- control programmes/health schemes;
- targeted testing/screening;
- ante-mortem and post-mortem inspections;
- laboratory investigation records;
- biological specimen banks;
- sentinel units;
- field observations;
- farm production records.

c) In addition, surveillance data should be supported by related information, such as:

i) data on the epidemiology of the *infection*, including environmental, and host and wild reservoir population distributions;

ii) data on farmed and wild animal movements and trading patterns for aquatic animals and aquatic animal products, including potential for exposure to wild aquatic animal populations, water sources or other contacts;

iii) national animal health regulations, including information on compliance with them and their effectiveness;

iv) history of imports of potentially infected material; and

v) biosecurity measures in place.

d) The sources of evidence should be fully described. In the case of a structured survey, this should include a description of the sampling strategy used for the selection of units for testing. For structured non-random data sources, a full description of the system is required including the source(s) of the data, when the data were collected, and a consideration of any biases that may be inherent in the system.

2. Critical elements

In assessing the quality of a surveillance system, the following critical elements need to be addressed over and above quality of *Competent Authority* (Chapter 1.4.3.).

a) Populations

Ideally, surveillance should be carried out in such a way as to take into account all animal species susceptible to the *infection* in a country, *zone* or *compartment*. The surveillance activity may cover all individuals in the population or part of them. Estimates of total population at risk for each species are required. When surveillance

is conducted only on a *subpopulation*, care should be taken regarding the inferences made from the results.

Definitions of appropriate populations should be based on the specific recommendations of the *disease* chapters of the *Aquatic Manual*.

b) Epidemiological unit

The relevant *epidemiological unit* for the surveillance system should be defined and documented to ensure that it is representative of the population or targeted *subpopulations* that would generate the most useful inferences about *disease* patterns. Therefore, it should be chosen taking into account factors such as carriers, reservoirs, vectors, immune status, genetic resistance and age, sex, and other host criteria.

c) Clustering

Infection in a country, *zone* or *compartment* usually clusters rather than being uniformly or randomly distributed through a population. Clustering may occur at a number of different levels (e.g. tank, pond, farm, or *compartment*). Clustering should be taken into account in the design of surveillance activities and the statistical analysis of surveillance data, at least at what is judged to be the most significant level of clustering for the particular animal population and *infection*.

d) Case and outbreak definitions

Clear and unambiguous case and outbreak definitions should be developed and documented for each *disease* under surveillance, using, where they exist, the standards in this Appendix and the *Aquatic Manual.*

e) Analytical methodologies

Surveillance data should be analysed using appropriate methodologies, and at the appropriate organisational levels to facilitate effective decision making, whether it be planning interventions or demonstrating status.

Methodologies for the analysis of surveillance data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different methodologies may be needed to accommodate the relevant pathogens, varying production and surveillance systems, and types and amounts of data and information available.

The methodology used should be based on the best available information that is in accord with current scientific thinking. The methodology should be in accordance with this Appendix and fully documented, and supported by reference to the scientific literature and other sources, including expert opinion. Sophisticated mathematical or statistical analyses should only be carried out when justified by the proper amount and quality of field data.

Consistency in the application of different methodologies should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding. The uncertainties, assumptions made, and the effect of these on the final conclusions should be documented.

f) Testing

Surveillance involves the detection of *disease* or *infection* by the use of appropriate case definitions based on the results of one or more tests for evidence of *infection* status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level (including field observations) may be described in terms of its sensitivity and specificity and predictive values. Imperfect sensitivity and/or specificity will have an impact on the conclusions from surveillance. Therefore, these parameters should be taken into account in the design of surveillance systems and analysis of surveillance data as described in the *Aquatic Manual*.

Although not determined for many aquatic *diseases*, sensitivity and specificity should be estimated as best as possible for a specific testing situation. Alternatively, where values for sensitivity and/or specificity for a particular test and testing situation are estimated in the *Aquatic Manual*, these values may be used as a guide.

Samples from a number of animals or units may be pooled and subjected to a testing protocol. The results should be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pool size and testing procedure.

g) Quality assurance

Surveillance systems should incorporate the principles of quality assurance and be subjected to periodic auditing to ensure that all components of the system function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the design.

h) Validation

Results from animal health surveillance systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.

i) Data collection and management

The success of a surveillance system is dependent on a reliable process for data

collection and management. The process may be based on paper records or computerised. Even where data are collected for non-survey purposes (e.g. during *disease* control interventions, inspections for movement control or during *disease* eradication schemes), the consistency and quality of data collection and event reporting in a format that facilitates analysis, is critical. Factors influencing the quality of collected data include:

- the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location;
- motivation of the people involved in the surveillance system;
- the ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;
- maintenance of disaggregated data rather than the compilation of summary data;
- minimisation of transcription errors during data processing and communication.

Article 3.8.1.4.

Structured population-based surveys

In addition to the principles for surveillance discussed above, the following guidelines should be used when planning, implementing and analysing surveys.

1. Types of surveys

Surveys may be conducted on the entire target population (i.e. a census) or on a sample. Periodic or repeated surveys conducted in order to document *disease* freedom should be done using probability based sampling methods (simple random selection, cluster sampling, stratified sampling, systematic sampling) so that data from the study population can be extrapolated to the target population in a statistically valid manner. Non-probability based sampling methods (convenience, expert choice, quota) can also be used. Recognising the inherent impracticalities in sampling from some aquatic populations, non-probability based sampling could be used when biases are recognised and used to optimise detection.

The sources of information should be fully described and should include a detailed description of the sampling strategy used for the selection of units for testing. Also, consideration should be made of any biases that may be inherent in the survey design.

2. Survey design

The population of *epidemiological units* should first be clearly defined; hereafter sampling

units appropriate for each stage, depending on the design of the survey, should be defined.

The design of the survey will depend on the size and structure of the population being studied, the epidemiology of the *infection* and the resources available.

3. Sampling

The objective of sampling from a population is to select a subset of units from the population that is representative of the population with respect to the object of the study such as the presence or absence of *infection*. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production systems. In order to detect the presence of an *infection* in a population of unknown *disease* status, targeted sampling methods that optimise the detection of *infection* can be used. In such cases, care should be taken regarding the inferences made from the results.

4. Sampling methods

When selecting *epidemiological units* from within a population the objectives of the surveillance system should be considered. In general, probability sampling (e.g. simple random selection) is preferable. When this is not possible, sampling should provide the best practical chance of generating optimal inferences about *disease* patterns in the target population.

In any case, the sampling method used at all stages should be fully documented and justified.

5. Sample size

In general, surveys are conducted either to demonstrate the presence or absence of a factor (e.g. *infection*) or to estimate a parameter (e.g. the prevalence of *infection*). The method used to calculate sample size for surveys depends on the purpose of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.

Article 3.8.1.5.

Structured non-random surveillance

Surveillance systems routinely use structured non-random data, either alone or in combination with surveys.

1. Common non-random surveillance data sources

A wide variety of non-random surveillance data sources may be available. These vary in their primary purpose and the type of surveillance information they are able to provide. Some surveillance systems are primarily established as *early detection systems*, but may also provide valuable information to demonstrate freedom from *infection*. Other systems provide cross-sectional information suitable for prevalence estimation, either once or repeatedly, while yet others provide continuous information, suitable for the estimate of

incidence data (e.g. *disease* reporting systems, sentinel sites, testing schemes).

a) Disease reporting or notification systems

Data derived from *disease* reporting systems can be used in combination with other data sources to substantiate claims of animal health status, to generate data for risk analysis, or for early detection. The first step of a *disease* reporting or notification system is often based on the observation of abnormalities (e.g. clinical signs, reduced growth, elevated mortality rates, behavioural changes, etc.), which can provide important information about the occurrence of endemic, exotic or new *diseases*. Effective laboratory support is, however, an important component of most reporting systems. Reporting systems relying on laboratory confirmation of suspect clinical cases should use tests that have a high specificity. Reports should be released by the laboratory in a timely manner, with the amount of time from *disease* detection to report generation minimised.

b) Control programmes/health schemes

Animal *disease* control programmes or health schemes, while focusing on the control or eradication of specific *diseases*, should be planned and structured in such a manner as to generate data that are scientifically verifiable and contribute to structured surveillance.

c) Targeted testing/screening

This may involve testing targeted to selected sections of the population (subpopulations), in which *disease* is more likely to be introduced or found. Examples include testing culled and dead animals, animals exhibiting clinical signs, animals located in a defined geographical area and specific age or commodity group.

d) Post-harvest inspections

Inspections of aquatic animal slaughter premises or processing plants may provide valuable surveillance data provided diseased aquatic animals survive to slaughter. Post-harvest inspections are likely to provide good coverage only for particular age groups and geographical areas. Post-harvest surveillance data are subject to obvious biases in relation to target and study populations (e.g. only animals of a particular class and age may be slaughtered for human consumption in significant numbers). Such biases need to be recognised when analysing surveillance data.

Both for traceback in the event of detection of *disease* and for analysis of spatial and population-level coverage, there should be, if possible, an effective identification system that relates each animal in the slaughter premises/processing plant to its locality of origin.

e) Laboratory investigation records

Analysis of laboratory investigation records may provide useful surveillance information. The coverage of the system will be increased if analysis is able to incorporate records from national, accredited, university and private sector laboratories. Valid analysis of data from different laboratories depends on the existence of standardised diagnostic procedures and standardised methods for interpretation and data recording. If available, the method listed in the *Aquatic Manual* in relation to the purpose of testing should be used. As with post-harvest inspections, there needs to be a mechanism to relate specimens to the farm of origin. It must be recognised that laboratory submissions may not accurately reflect the *infection* or *disease* situation on the farm.

f) Biological specimen banks

Specimen banks consist of stored specimens, gathered either through representative sampling or opportunistic collection or both. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from *infection*, and may allow certain studies to be conducted more quickly and at lower cost than alternative approaches.

g) Sentinel units

Sentinel units/sites involve the identification and regular testing of one or more of animals of known health/exposure status in a specified geographical location to detect the occurrence of *disease*. They are particularly useful for surveillance of *diseases* with a strong spatial component, such as vector-borne *diseases*. Sentinel units provide the opportunity to target surveillance depending on the likelihood of *infection* (related to vector habitats and host population distribution), cost and other practical constraints. Sentinel units may provide evidence of freedom from *infection*, or provide data on prevalence and incidence as well as the distribution of *disease*. Cohabitation with a susceptible population should be considered for testing *infection* or *disease* in populations of valuable animals, the lethal sampling of which may be unacceptable (e.g. ornamental fish).

h) Field observations

Clinical observations of epidemiological units in the field are an important source of surveillance data. The sensitivity and/or specificity of field observations may be relatively low, but these can be more easily determined and controlled if a clear, unambiguous and easy to apply standardised case definition is applied. Education of potential field observers in application of the case definition and reporting is an important component. Ideally, both the number of positive observations and the total number of observations should be recorded.

i) Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of *disease* at the population level. If production records are accurate and consistently maintained, the sensitivity of this approach may be quite high (depending on the *disease*), but the specificity is often quite low.

2. Critical elements for structured non-random surveillance

There is a number of critical factors that should be taken into account when using structured non-random surveillance data such as coverage of the population, duplication of data, and sensitivity and specificity of tests that may give rise to difficulties in the interpretation of data. Surveillance data from non-random data sources may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.

3. Analytical methodologies

Different scientifically valid methodologies may be used for the analysis of non-random surveillance data. This most often requires information on parameters of importance to the surveillance system, such as sensitivity and specificity. Where no such data are available, estimates based on expert opinions, gathered and combined using a formal, documented and scientifically valid methodology may be used.

4. Combination of multiple sources of data

The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented including references to published material.

Surveillance information gathered from the same country, *zone* or *compartment* at different times (e.g. repeated annual surveys) may provide cumulative evidence of animal health status. Such evidence gathered over time may be combined to provide an overall level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-random sources, may be able to achieve the same level of confidence in a shorter period of time.

Analysis of surveillance information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take into account the decreased value of older information. The sensitivity, specificity and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

Surveillance to demonstrate freedom from disease/infection

1. Demonstration of freedom from infection

A surveillance system to demonstrate freedom from *infection* should meet the following requirements in addition to the general requirements for surveillance outlined in Article 3.8.1.3 of this Appendix.

Freedom from *infection* implies the absence of the pathogenic agent in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of the absence of *infection*. Demonstrating freedom from *infection* involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Member Countries) that *infection* with a specified pathogen is not present in a population. In practice, it is not possible to prove (i.e. be 100% confident) that a population is free from *infection*. Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that *infection*, if present, is present in less than a specified proportion of the population.

However, apparent *infection* at any level in the target population automatically invalidates any freedom from *infection* claim unless the positive test results are accepted as false positives based on specificity values described in the relevant *disease* chapter.

2. Requirements to declare a country, zone or compartment free from *disease/infection* without pathogen specific surveillance

This Article provides general principles for declaring a country, *zone* or *compartment* free from *disease/infection* in relation to the time of last occurrence and in particular for the recognition of historical freedom.

The provisions of this Article are based on the principles described in Article 3.8.1.3. of this Appendix and the following premises:

- in the absence of *disease* and vaccination, the farmed and wild animal populations would become susceptible over a period of time;
- the *disease* agents to which these provisions apply are likely to produce identifiable clinical signs in observable susceptible animals;
- competent and effective *Competent Authority* will be able to investigate, diagnose and report *disease*, if present;
- the absence of *disease/infection* over a long period of time in a susceptible population can be substantiated by effective *disease* investigation and reporting by a Member Country.

a) Absence of susceptible species

Unless otherwise specified in the relevant *disease* chapter, a country, *zone* or *compartment* may be recognised as being free from *infection* without applying *targeted surveillance* if there are no susceptible species (as listed in the relevant chapter of this *Aquatic Manual*, or in the scientific literature) present in that country, *zone* or *compartment*.

b) Historically free

Unless otherwise specified in the relevant *disease* chapter, a country, *zone* or *compartment* may be recognised free from *infection* without formally applying a pathogen-specific surveillance programme when:

i) there has never been a substantiated occurrence of *disease* reported officially or in the scientific literature (peer reviewed), or

ii) eradication has been achieved or the *disease/infection* has ceased to occur for at least 25 years,

provided that for at least the past 10 years:

iii) the *basic biosecurity conditions* are in place and effectively enforced;

iv) no vaccination against the *disease* has been carried out unless otherwise allowed for in the *Aquatic Code*;

v) *infection* is not known to be established in wild aquatic animals within the country or *zone* intended to be declared free. (A country or *zone* cannot apply for historical freedom if there is any evidence of *infection* in wild aquatic animals. However, specific surveillance in wild aquatic animals is not necessary.)

A country, *zone* or *compartment* that was self-declared free on the basis of the absence of susceptible species, but subsequently introduces any of the susceptible species as listed in the *Aquatic Manual*, may be considered historically free from the *disease* provided that:

- the country, *zone* or *compartment* of origin was declared free of the *disease* at the time of introduction,
- *basic biosecurity conditions* were introduced prior to the introduction,
- no vaccination against the *disease* has been carried out unless otherwise allowed for in the *disease* specific chapter of this *Aquatic Code.*

c) Last occurrence within the previous 25 years

Countries, *zones* or *compartments* that have achieved eradication (or in which the *disease/infection* has ceased to occur) within the previous 25 years, should follow the pathogen-specific surveillance requirements in the *Aquatic Manual* if they exist.

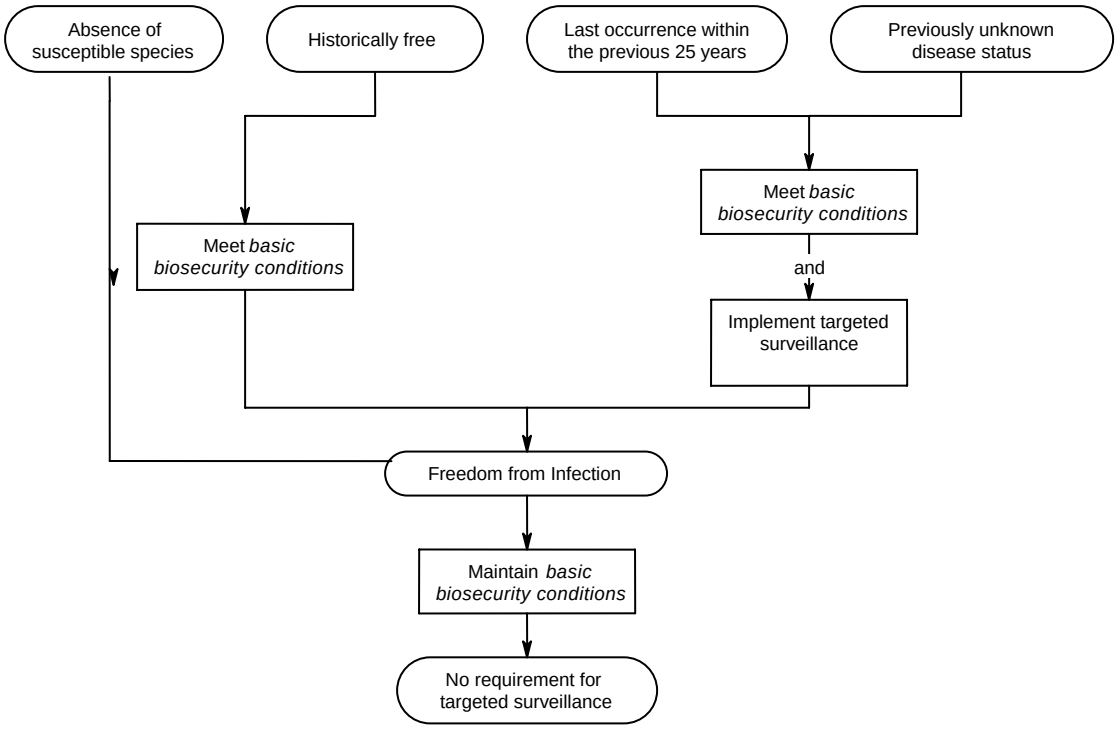
In the absence of *disease* specific information to aid the development of a surveillance system, declaration of *disease* freedom should follow at least 2 surveys per year (for at least 2 consecutive years) to be conducted 3 or more months apart, at the appropriate life stage and at times of the year when temperature and season offer the best opportunity to detect the pathogen. Surveys should be designed to provide an overall 95% confidence and with a design prevalence at the animal and higher (i.e. pond, farm, village, etc.) levels being 2% or lower (this value may be different for different *diseases* and may be provided in the specific *disease* chapter in the *Aquatic Manual*). Such surveys should not be based on voluntary submission and should be developed following the guidelines provided in the *Aquatic Manual*. Survey results will provide sufficient evidence of *disease* freedom provided that for at least the past 10 years these additional criteria are met:

i) the *basic biosecurity conditions* are in place and effectively enforced;

ii) no vaccination against the *disease* has been carried out unless otherwise provided in the *Aquatic Code*;

iii) *infection* is not known to be established in wild aquatic animals within the country or *zone* intended to be declared free. (A country or *zone* cannot apply for freedom if there is any evidence of *infection* in wild aquatic animals. Specific surveillance in wild aquatic animals of susceptible species is necessary to confirm absence.)

The different paths to recognition of freedom from *infection* are summarised in the diagram below.



2. Guidelines for the discontinuation of pathogen-specific surveillance after recognition of freedom from infection

A country or *zone* that has been recognised as free from *infection* following the provisions of the *Aquatic Code* may discontinue pathogen-specific surveillance while maintaining the *infection*-free status provided that:

a) the *basic biosecurity conditions* are in place and effectively enforced;

b) vaccination against the *disease* is not applied;

c) Surveillance has demonstrated that *infection* is not present in wild aquatic animal populations of susceptible species.

A special case can be made for a *compartment* located in a country or *zone* that is not proven to be free from *infection* if surveillance is maintained and exposure to potential sources of *infection* is prevented.

3. International recognition of disease/infection free status

For *diseases* for which procedures exist whereby the OIE can officially recognise the existence of a *disease/infection* free country, *zone* or *compartment*, a Member Country wishing to apply for recognition of this status shall, via its Permanent Delegate, send to the OIE all the relevant documentation relating to the country, *zone* or *compartment* concerned. Such documentation should be presented according to guidelines prescribed by

the OIE for the appropriate animal *diseases*.

Article 3.8.1.7.

Surveillance for distribution and occurrence of infection

Surveillance to determine distribution and occurrence of *infection* or of other relevant health related events is widely used to assess the prevalence and incidence of selected *disease/infection* as an aid to decision making, for example implementation of control and eradication programmes. It also has relevance for the international movement of animals and products when movement occurs among infected countries.

In contrast to surveillance to demonstrate freedom from *infection*, surveillance for the distribution and occurrence of *infection* is usually designed to collect data about a number of variables of animal health relevance, for example:

a) prevalence or incidence of *infection* in wild or cultured animals;

b) morbidity and mortality rates;

c) frequency of *disease/infection* risk factors and their quantification;

d) frequency distribution of variables in *epidemiological units*;

e) frequency distribution of the number of days elapsing between suspicion of *infection* and laboratory confirmation of the diagnosis and/or to the adoption of control measures;

f) farm production records, etc.